UNITED STATES DISTRICT COURT
DISTRICT OF PENNSYLVANIA

USA, et al.,	)	10-CV-04374-CFK
	)	
Plaintiff,	)	
vs.	)	**UNDER SEAL**
	)	
	)	
MERCK & CO., INC.,	)	Philadelphia, PA
	)	January 24, 2023
Defendant.	)	10:11 a.m.
	)	

UNDER SEAL TRANSCRIPT OF MOTION HEARING
BEFORE THE HONORABLE CHAD F. KENNEY
UNITED STATES DISTRICT JUDGE

APPEARANCES:

For the Plaintiffs:

GORDON SCHNELL, ESQUIRE
DANIEL J. VITELLI, ESQUIRE
CONSTANTINE, CANNON, LLP
335 Madison Avenue, 9th Fl.
New York, NY 10017

KATHLEEN R. SCANLAN, ESQUIRE
KELLER, GROVER, LLP
1965 Market Street
San Francisco, CA 94103

JOHN A. MACORETTA, ESQUIRE
SPECTOR, ROSEMAN & KODROFF, P.C.
2001 Market Street
Suite 3420
Philadelphia, PA 19103

JOEL M. SWEET, ESQUIRE
U.S. ATTORNEY'S OFFICE
615 Chestnut Street
Suite 1250
Philadelphia, PA 19106

For the Defendants:

JESSICA ELLSWORTH, ESQUIRE
HOGAN. LOVELLS
555 Thirteenth Street
Columbia Square
Washington, DC 20004

APPEARANCES (Cont'd.):

For the Defendants:

LISA DYKSTRA, ESQUIRE
R. BRENDAN FEE, ESQUIRE
MORGAN, LEWIS & BOCKIUS, LLP
1701 Market Street
Philadelphia, PA 19103

DINO S. SANGIAMO, ESQUIRE
VENABLE, LLP
750 E. Pratt St., Suite 900
Baltimore, MD 21202

Audio Operator: Chris Kurek

Transcribed by:

DIANA DOMAN TRANSCRIBING, LLC
P.O. Box 129
Gibbsboro, New Jersey 08026-0129
Office: (856) 435-7172
Fax: (856) 435-7124
Email: dianadoman@comcast.net

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I N D E X

(The following was held in open court at 10:11 a.m.:)

COURTROOM DEPUTY: All rise, please. The United States District Court is now in session, the Honorable Chad F. Kenney presiding.

THE COURT: Good morning, everyone.

ALL COUNSEL: Good morning, Your Honor.

THE COURT: All right. This is Merck -- in re: Merck and U.S., ex rel, Krahling and, what is it, Wlochowski vs. Merck, and we're going to start with that one, 4374-10. And then we'll follow right up with 355 of 12, and that's in re: Merck, the antitrust litigation.

So in 43, the 10:00 argument, 4374-10, counsel for the record?

MR. SCHNELL: Gordon Schnell from Constantine, Cannon for Relators.

MR. VITELLI: Good morning, Your Honor. Daniel Vitelli, also of Constantine, Cannon, counsel for the Relators.

MS. SCANLAN: Good morning, Your Honor. Kathleen Scanlan, also for the Relators.

MS. ELLSWORTH: Good morning, Your Honor. Jessica Ellsworth of Hogan, Lovells, for Merck.

MS. DYKSTRA: Good morning, Your Honor. Lisa Dykstra, Morgan, Lewis, for Merck.

MR. SANGIAMO: Good morning, Your Honor. Dino Sangiamo of Venable for Merck.

MR. FEE: Good morning, Your Honor. Brendan Fee from Morgan, Lewis, also for Merck.

THE COURT: All right. Everybody can have seat.

MR. SWEET: Your Honor, Joel Sweet, for the United States.

THE COURT: Okay. Good morning. And there was somebody here from GSK, I was told?

MR. COLVIN: Good morning, Your Honor. David Colvin, on behalf of the non-party, GSK.

THE COURT: And you're asking for certain parts of the transcript to be restricted?

MR. COLVIN: I am, Your Honor. Would it be helpful if I approach the microphone for the record?

THE COURT: No, it wouldn't be.

MR. COLVIN: Okay.

THE COURT: We can hear you from there.

MR. COLVIN: Okay. Yes, Your Honor. As I understand it, GSK figures to play a central role in one or both hearings today, based on documents and deposition testimony that GSK provided in response to subpoenas served by the parties in these matters.

THE COURT: All right. So, this is what we're going to do, we're going to -- we will seal the transcript

initially. All right. After you get the transcript, you will have 30 days to redact what will be made -- redact from the transcript what you claim is confidential. So there will be a sealed full version of the transcript. And then the public transcript will have your redactions in it as to confidential information. You do want to read the Third Circuit -- which I'm sure you have -- the Third Circuit rulings on what is confidential information.

MR. COLVIN: Of course, Your Honor.

THE COURT: Okay. That's how we'll handle it.

MR. COLVIN: Of course, Your Honor. And with respect to the courtroom, today, Judge, it's my understanding that one or more parties may be publishing on the screen documents that contain sensitive and proprietary information that belongs to GSK. It was designated under the protective order, in place, entered by the Court, as confidential and having confidential, and so we would object to that, unless the Court were to close the courtroom for purposes of this hearing.

THE COURT: I'm not closing the courtroom, so I don't know how you want to handle it.

Is there anybody in here taking confidential information that they're going to use for producing something, some vaccine?

MR. MACORETTA: Your Honor, John Macoretta, here,

for the private plaintiffs. We will talk about some things, GSK. We have -- their motion is that we have no basis for GSK doing what they did. To defend that, we have to show some GSK documents and testimony. We can avoid putting it on the screen, but it's kind of hard to defend the motion without talking about it.

THE COURT: All right. You can talk about it. We won't put it on the screen.

MR. COLVIN: Thank you.

THE COURT: All right. So here we are. We're ready to go, a motion for summary judgment, right, and it's rather lengthy.

MR. SCHNELL: Your Honor, we had moved for summary judgment, as well. There are cross-motions.

THE COURT: You have cross-motions for summary judgment. Yes, I saw that. All right.

So, are you ready to begin? You can sit at your chair. You don't have to come up here.

MS. ELLSWORTH: Okay.

THE COURT: Are you comfortable doing that?

MS. ELLSWORTH: It's unusual to address the Judge seated, but I'm happy to do so if Your Honor is --

THE COURT: Well, welcome to my courtroom. You stood -- everybody stood. We got the standing part over. I need the substance part. So, if you're comfortable,

sometimes, it makes it easier, and you have your co-counsel there. So that's helpful, too. So, go ahead, you can give me the preliminaries.

THE COURT: Thank you.

Good morning, Your Honor, may it please the Court, Jessica Ellsworth, for Merck, and I would like to reserve a small bit of time to respond to what the Government may say and also what the Relators may say in this case.

As I'm sure the Court is aware, everything was filed under seal for the summary judgment briefs, and our view is that the Court does not need to conduct this hearing under seal. It's a summary judgment hearing. Most of the evidence is quite dated, at this point, and FDA has approved GSK's Mumps vaccine. So, I think we're all on the same page about that.

If I could, Your Honor, I'd like to hand up to you a set of slides that I'll walk through with the Court. May I approach?

(Pause in proceedings.)

THE COURT: Sure.

MS. ELLSWORTH: Your Honor, the briefs cover a lot of ground in this case, but we believe the summary judgment can and should be granted on a number of grounds, including the evidence created -- does not create a triable fact as to falsity and materiality and scienter.

But given the shortness of time, I'd like to focus, today, on the argument we think is most obvious and undisputable as a reason to grant summary judgment for Merck, and that is materiality.

So if you open the slides to page two, you see a graph --

THE COURT: You want to start, where, with what?

MS. ELLSWORTH: Materiality.

THE COURT: That's where I wanted you to start, and that's, really, what I want you to address, so go ahead.

MS. ELLSWORTH: Thank you, Your Honor.

Slide two is a graphical depiction of what has happened with reported cases of Mumps in this country since Merck's Mumps vaccine was approved by FDA in 1967, and I think that's important context to have in mind as we go through the argument this morning.

The False Claims Act has a number of elements, falsity and materiality, causation and scienter. They are set out on page three. But materiality is what I really want to focus on. What is materiality? Materiality is what polices the line between matters of regulatory compliance or breach of contract and actionable False Claims Act cases.

So if we turn to slide five -- excuse me -- turn to slide four, you will see why this line is important. The FCA exists to protect the Government from paying fraudulent

claims, not to allow Relators to second guess Agency judgment or ask lay jurors to do so. And so materiality looks at what the Supreme Court described as the likely or actual behavior of the recipient of any alleged misrepresentation.

In other words, it asks whether the Agency would have actually or likely done anything differently as a result of a compliance issue that the Relators are alleging. Escobar emphasizes it's a demanding standard. It's a rigorous standard. It should be strictly enforced, and that it is not too fact-intensive to address at summary judgment.

So as the Court looks at the summary judgment record, the Court should ask a straightforward question, and that is whether there is any non-speculative evidence. And the non-speculative part of that is important, because to avoid summary judgment, the Relators need more than speculation or innuendo.

Is there any non-speculated evidence that CDC would have made different purchasing choices in the Vaccine for Children Program, based on Relators' opinions about a research study known as Protocol-7 or based on Relators' opinions about the meaning of a single, internal, unverified potency loss model that conflicted with actual stability data? The answer is, no, there is no non-speculative evidence that CDC would have made any different purchasing choices related to M-M-R II or ProQuad. Those are Merck's two combination vaccines that

have the Mumps vaccine as a component.

If we turn to slide six, I want to briefly pause to make clear that there are two agencies discussed in the briefing, the FDA and the CDC. The FDA's mission is to protect public health by insuring the safety and efficacy of drugs, including Merck's Mumps vaccine. FDA oversees drug approval, licensing, labeling, stability testing and manufacturing practices. And it has an array of enforcement authority.

CDC's mission is to fight and track diseases and protect people from health threats. For decades, the CDC has bought Merck's Mumps vaccine, and the Vaccine for Children Program, based on recommendations from its internal advisory committee on immunizations practices, a group of medical and public health experts that study using vaccines to control diseases.

During the summary judgment briefing, to try to save their case, the Relators repeatedly and expressly disclaimed that they are pursuing a fraud on the FDA theory. You can see that in their response to our motions and in the reply on their own motion. That disclaimer makes this Court's job easier. Every time the Relators stand up -- or sitting down this morning -- and point you to a piece of evidence, you should ask yourself if it relates to communications or obligations between Merck and the CDC.

If it, instead, relates to whether FDA should or would have done something differently, it falls within the theory that Relators have disclaimed, and it cannot save their case.

If we move to slide seven, this is relevant timeline for the materiality question. 22 years ago, which, to give you a sense of time, is the year George W. Bush was sworn in as President, FDA issued a warning letter to Merck involving some lots of Mumps vaccine that predated a formulation change and had dropped below the labeled potency, which was a potency level Merck had always understood to be the release potency and not the potency at expiration.

Before this warning letter issued, Merck had already raised its release potency to a level that FDA had requested, which is the potency used today. Also, in 2001, one of the Relators called FDA to raise concerns that Merck was committing fraud in the lab he worked in, which was conducting Protocol-7.

FDA investigated those claims for months and reached an agreement with Merck on what data from Protocol-7 could be used in connection with labeling changes for M-M-R II and a later approval of ProQuad, Merck's new quadrivalent vaccine. You fast-forward to 2010, and the Relators filed this suit, alleging that Protocol-7 showed the Mumps vaccine was not as efficacious as it had been back in 1967, when Dr. Hilleman

conducted his pathbreaking studies that led to FDA's approval.

The Government invested those allegations, and it declined. What followed was years of fact and expert discovery, during which the Government had access to all of the materials in this case, attended, participated in depositions, authorized CDC witnesses to be deposed, and even authorized former CDC employees to be experts for Merck.

Then, in 2019, the Court authorized Relators expert, a former FDA Commissioner named Dr. Kessler, to go directly to public health officials at FDA and CDC and offer his opinions and conclusions about why the discovery record here showed concerns about the Mumps vaccine that the agencies didn't know about. This submission went directly to the Director of the CDC and the Commissioner of the FDA, among others.

It attached and discussed dozens of exhibits from the discovery record and Dr. Kessler's analysis of those issues. Today, it's 2023. I checked the CDC's website this morning. After more than two decades of hearing these Relators and their experts' complaints, the CDC's very public position is that the Mumps component of M-M-R II and ProQuad is "very effective", with an average effectiveness of 88 percent when administered as recommended.

In other words, two decades later, the CDC has not changed its views about the vaccine one whit as a result of the complaint filed by these Relators.

If we move to slide eight, I want to emphasize the Court's order authorizing this submission to the CDC and FDA for two reasons. One is, it's fairly unique. And two, it's very important to the materiality question before the Court. At the hearing that led to this order, which had to do with whether Dr. Kessler could take certain opinions public, the Court took the position that it was the expert agencies who should look at Dr. Kessler's professed concerns about the vaccine, based on what he saw in discovery.

By going to public health officials at these expert agencies, the Court said that the agencies could evaluate his concerns, decide whether they are valid, and decide whether they warrant any action by the agencies. On October 23rd, 2019, this submission went directly to public health officials at CDC and FDA, including, as I mentioned, the CDC Director and the FDA Commissioner.

We are now three years and three months later. The CDC and FDA have taken no action in response to Dr. Kessler's professed opinions, concerns and conclusions.

If we look at slide nine, this tells us a lot about why. It is a reflection of the undisputed real world impact of this vaccine. Before the vaccine was approved, there was an average of 186,000 cases of Mumps every year. If you multiply 186,000 times 23 years, the time period between 2000 and 2022, that would equal almost 4.3 million cases of Mumps.

But with the vaccine, how many cases of Mumps have there been? In actuality, there have been just over 37,000 cases reported. And so the undisputed real world impact is that there has been a 99.1 percent reduction in cases of Mumps from the pre-vaccine era. The timeline we were discussing and this data on impact point in the same direction.

Despite everything that Relators and their experts have said, FDA and CDC stand squarely behind this vaccine and for a very good reason. In fact, for more than 4.2 million reasons, just counting the individuals who avoided Mumps in the years since Relators started their campaign against this vaccine.

If you move to slide 11 to 13, I want to make clear that CDC has had full knowledge of the record in this case, and yet, it's public statement of support on its website, including that the vaccine is 88 percent effective, when administered as recommended, has not changed, and we quote those websites on those slides so you can see that for yourself.

The FDA's public statements of support haven't changed either, and you can see that on slides 14 and 15. In fact, the person who made the statement from FDA -- it's listed on slide 14 -- was also a recipient of Dr. Kessler's submission, Peter Marks, from FDA.

So after Peter Marks said that he could not state

strongly enough the overwhelming scientific evidence shows the vaccines are among the most effective and safest inventions to prevent illness and protect public health, that the vaccine was very effective at protecting against Mumps, and that the FDA had 50 years of experience and evidence supporting that fact. He received the Kessler submission, and he didn't take that statement back. He didn't say anything in response.

In reality, the CDC's purchasing patterns have not changed on bit. The FDA approved a new Mumps vaccine last year, manufactured by GSK, after concluding that that vaccine was non-inferior to Merck's vaccine. No one at either agency asked Merck to reprove the bonafides of its vaccine. No one sent a "dear doctor" letter to providers. No one rescinded the FDA approval. No one asked Merck to conduct additional research trials. No one asked for a recall. No one asked for more stability testing. No one asked for even a single batch of vaccine to be traced because of some concern about potency or efficacy.

All of this matters a great deal. We're here more than three years after Relators laid out their best case for their truly bold claim that Merck lacks any data its Mumps vaccine works.

Back at the motion to dismiss stage, the Relators could get away with telling Judge Jones that he didn't know what he didn't know, and they needed a chance to develop the

facts. Well, here we are more than a decade older and wiser, after a newly coined theory of the case during discovery, with millions and millions of pages that Merck produced, dozens of fact and expert witnesses deposed, including from the CDC, itself, and quite literally, nothing left to be discovered with regard to the complaint's allegations.

The Government has followed all of it. They know everything the Relators have discovered. They have seen everything the Relators have to offer, and yet, nothing has changed about the agencies' opinion of the Mumps vaccine. Both FDA and CDC still fully embrace this vaccine.

Despite all of this discovery, Relators have no evidence that CDC would have stopped buying M-M-R II or ProQuad based on their complaints about Protocol-7 or the internal potency loss model. On Protocol-7, the CDC witnesses pointed to FDA as the agency that evaluates manufacturer clinical research data as part of licensing and made clear that CDC's own evaluation of effectiveness data is what is most important to the agency, not clinical research trials relating to licensing, which is in FDA's bailiwick of responsibility.

On potency, certain losses of M-M-R II did actually dip below the labeled potency in the late 1990s, when Merck understood the label's potency to be a release potency, just as it had going back to 1967. But when that happened, FDA did

not ask Merck to recall those lots. It issued a warning letter. That warning letter says that it would be shared with contracting agencies, like the CDC, and the CDC paid for and continued buying the vaccine at the statutorily capped price.

The Relators have no evidence, no testimony from a single CDC witness that would allow them to show materiality. I invite the Court to ask them to identify for you any CDC witness testimony that says CDC would have stopped paying for the Mumps vaccine based on a single immunogenicity study, Protocol-7, or based on a single potency model that Merck had already told the FDA about. They didn't identify it in their papers, and they won't be able to today.

We turn to slide 18. This underscores why all of this is significant. The Relators cannot show a triable issue of fact on materiality. How on Earth can they go to a jury and say CDC would have made different purchasing decisions, despite all the real world effectiveness and impact data, based on Protocol-7, which FDA oversaw, or an internal potency loss model, which Merck told FDA about and turned out to be inconsistent with real world stability data? The answer is that there is no evidence creating a dispute of fact on materiality.

Under the Supreme Court's decision in Escobar and materiality decisions from around the country, this is exactly the sort of fact pattern on which summary judgment must be

granted. And I want to just talk about the holistic analysis that Escobar says this Court should conduct.

One of the things to look at are continued purchases, which we have been discussing this morning. Continued purchases can be strong evidence that the materiality standard is not met, when those purchases are made with knowledge. We think there is such evidence of knowledge here, based on the record in this case, the submission that Dr. Kessler made directly to public health officials at the CDC and the FDA, going all the way back to the warning letter in 2001. It discussed actual lots of vaccine falling below the labeled potency, and Protocol-7, which the FDA interacted with Merck about every aspect of.

The reality is, the CDC has negotiated 22 annual contracts with Merck since Relator Krahling called the FDA to report his concerns about Protocol-7. CDC has negotiated 12 of those since the complaint was filed, five of those since fact discovery ended and three of those since Relators sought summary judgement, presented their best version of their story to the Court, to the CDC, to FDA, and the CDC's purchases have continued.

This kind of unwavering position renders it implausible, in the words of the First Circuit in it's Nagle decision. It renders -- it substantially increases the burden on Relators, in the words of the Fifth Circuit, in its Harmon

decision, and it precludes Relators from pursuing these claims, in the words of the D'Agostino decision.

To take the D.C. Circuit's view, when the Court had the benefit of hindsight, which it does in this case, it should not ignore what actually occurred. So that's the continued purchases bucket. What else is there? Because materiality is a holistic inquiry. And I would note, on continued purchases, all of those cases that I just mentioned are ones that the United States' statement of interest did not discuss those holdings and did not discuss the outcome in those cases.

That moves us to the other buckets of information that could show materiality or could show there is a triable fact. Here, there is no statute, no regulation and no contract provision that expressly conditions the CDC's payment on Mumps vaccine exceeding some specific efficacy rate or some specific potency level.

This question about statutes, regulations and contracts with such express conditions was an issue in Escobar because the Circuits had split on whether courts should be differentiating between conditions of payment and conditions of participation. And what the Court said in Escobar is that, even where we have an expressed condition of payment, that, alone, is not enough to show materiality or trying to figure out what the agency would actually have done.

In this case, there is not the kind of statute, regulation or contract provision that contains the express provision that Escobar was talking about. Efficacy, from what the record shows, is not a procurement criteria. It was not written into the contract as a criteria, and it never came up in contract negotiations. Potency is, likewise, not a condition of payment.

The Relators try to point to certain contract provisions about CGMP regulations, which are manufacturing requirements that FDA supervises, a shelf life requirement, but that, really, is just about when the expiration date is, and a warranty of merchantability, which just asks whether there was, in fact, an FDA license, which there was, and the Relators have disclaimed that they are trying to show that that license was obtained fraudulently.

So that leaves us, in this case, in the same situation that this Court identified in the Dr. Reddy's case, where there is no statutory, regulatory or contractual provision that makes statements about efficacy or potency a condition of Government payment.

The next factor is whether this -- whether there is any evidence that the CDC consistently refuses to pay claims in the mine run of cases, based on non-compliance with the particular statutory, regulatory or contractual requirement at issue here.

First of all, there is not a mine run of cases about these kinds of allegations. So the Relators have pointed to a bunch of other types of enforcement action that DOJ and the FDA sometimes take related to misbranded and adulterated drugs, related to the Anti-Kickback Statute, related to a whole bunch of other types of enforcement, but there is no example of a case in which CDC has refused to pay for an FDA-approved drug as insufficiently protected. They just don't have one.

They have no example of a case in which any relevant, regulatory agency was on notice of the basis of Relators' allegations for more than two decades, while it continued entering annual contracts to purchase the product, all the while making public statements about the product's effectiveness and impact and without making any comment or raising any concern to the manufacturer. Simply, there is no other record evidence that could create a triable fact as to materiality.

Two brief final legal points. One is that courts presume Executive Branch agencies and employees are discharging their duties. That's the presumption of regularity. Here, FDA and CDC's duties include analyzing the validity of serious public health allegations levied by Relators and their former FDA Commissioner paid expert and adhering to the agencies' duties to inform the public of

vaccine safety concerns. That presumption of regularity should lead this Court to grant summary judgment for Merck on its materiality argument.

The second legal point I want to make is that, as a legal matter, if FDA concluded that Dr. Kessler's 2019 submission or anything else in this record presented "new information" that should be reflected on the label, FDA was statutorily obligated to take action. That's 29 U.S.C. Section 355(O)(iv)(a), and we cited that in our response to the Government's statement of interest at page eight, footnote five.

We are simply past the point where FDA's continued purposeful inaction can mean nothing. In fact, it means something, and it means something as a matter of law. The indisputable record shows FDA has kept the label as it is, knowing full well the specifics of the evidence in this case, and CDC's purchasing patterns and related conducts have remained steady, in spite of knowledge of all of the evidence in this case.

For these reasons, we ask the Court to grant summary judgment for Merck on materiality and end this case.

THE COURT: Thank you, Counsel.

Counsel?

MR. SCHNELL: Thank you, Your Honor.

The one thing missing from -- the one big thing

missing from Merck's counsel's presentation was any discussion of the evidence. So, let's talk about the evidence, give you a sense of what this case is really about, and then I can talk about materiality, but I think that's an important backdrop.

so, it starts when Merck discovered pervasive potency problems with its marquis vaccine for Mumps, M-M-R II. And these were problems that were so serious that it raised within Merck the alarm that they better fix it or they were going to be subject to a product recall.

The first thing they tried was to double the Mumps potency to address this problem, and they did that with the FDA's knowledge. It was the FDA's suggestion, so they doubled the Mumps potency. It didn't help. They still had Mumps potency failures that they could not meet the minimum potency specifications in the product label for the full 24-month shelf life. This raised the alarm within Merck to the highest levels, which they did not share with the FDA, the highest level so much that the documents that we have presented on summary judgment -- part of the reason why we're moving for summary judgment -- is that Merck internally recognized in their own words that the product was misbranded, Merck's words, out of compliance, Merck's words, non-marketable, Merck's words. All of those documents are in the record, but Merck is not mentioning those.

So what do they need to do? They needed to lower

the Mumps potency specification to get it back into compliance. Again, none of this was shared with the FDA, let alone with the CDC. So Protocol-7, the clinical trial at issue in this case, was the clinical trial Merck needed to pass to get its product back into compliance and avoid a product recall. The documents are clear, at the highest levels of the company, they were concerned about a recall. It was not shared with the FDA or the CDC.

So, Merck started on Protocol-7 with standard regular testing. What they needed to show with Protocol-7 was that the lower potency specification that they wanted to get to to bring the product back into compliance, the Mumps vaccine still afforded sufficient protection. Standard testing showed they weren't even close.

So, what do they do? They engaged in a results-oriented design of a test that would guarantee they reached the result they needed. Dr. Krall (ph) was the Chief Scientist at Merck who ran this study, who designed this study, who ran the lab that did the study, and we deposed him. He admitted that he created a results-oriented test to get the results that we needed -- that Merck needed.

That didn't work either, and that's when they had to resort to falsifying data, destroying unfavorable data. Our Relators were there in the lab. They saw it firsthand. There is no dispute that this did not happen, and the FDA inspection

that was prompted by one of our Relators was a result of that. But what Merck is not saying is that even during this inspection, Merck lied to the FDA to get out of it, to get out of the problem. Our Relator was there. Both of them were there. They overheard the lies. We have documents that show the lies to the FDA to get out of this inspection.

So, they continue with Protocol-7, and what do you have at the end of the day, because of the manipulation and designing of the test and the falsification of data, you have a completely inaccurate and unreliable test, a clinical trial, that had nothing to do with measuring protection. And you don't have to take our word. This whole presentation, our whole summary judgment motion isn't based on our word. It's based on Merck's documents, the witnesses' testimony and their own experts. Their own experts support virtually everything we're saying.

And so, I just want to walk through with you, just take a minute, these are what Merck's witnesses and experts have said about Protocol-7. We'll start with Joe Antonello. He's the chief biostatistician involved in Protocol-7. What he said is -- his words -- the precision of the test was "very poor". The test had "no clinical history expectation or meaning".

Florian Schodel, very high up in Merck vaccine research, this is what he said, "could not overemphasize the

weakness of the test." Another one of his quotes, "very unreliable".

Emilio Emini, another high up executive in Merck research called the test "very artificial". David Krall, again, the gentleman who designs the test and ran the test, we asked him at his deposition whether the test was even accurate. He said, "that's beyond my expertise to answer." The guy who designed the test and ran the test couldn't even answer whether it was accurate.

We asked the same question to Merck's 30(b)(6) corporate representative, Barbara Kuter, another executive high up in Merck's vaccine research. We asked if the testing "had any relationship to protection from disease". That's what the whole point of the test was. And her answer, "I really can't answer that." This is Merck's corporate representative. But it doesn't stop there.

We asked Marcela Pacetti, one of Merck's experts, who specializes in this kind of testing, her words, "Protocol-7 did not include a proper analysis of vaccine efficacy or effectiveness." That was the whole point of the test. William Atkinson, another one of Merck's experts said this, the testing "would not have really anything to do with effectiveness."

This is what their own people are saying about the clinical trial that they were using to support licensure of

this Mumps vaccine. Our experts are in complete accord with these opinions. David Kessler, who Merck's counsel referenced, a former FDA Commissioner and who, until just last week, was the Chief Science Officer for the Government's COVID Task Force, said this about the test, his words, "a mess, with no clinical relevance."

Peter Calcott, another one of our experts, who was the head of quality for a major vaccine manufacturer said this, "The test had no technical validity. It was meaningless." There is undisputed evidence that Protocol-7 was essentially garbage, yet, Merck represented it to every constituency in the opposite way, saying that it proved that the vaccine at the lower potency was effective.

It's what they told the parents -- and this is all in the record. I can stop at any point to show you a document, but it's all in our papers, and that's why we're moving for summary judgment here, Your Honor. It told the parents of the children who were the subjects of the tests that the test was going to show your child is protected.

It's what they told the doctors who were administering the shots on these kids that the test is going to show these kids are protected. It's what they told the DOJ when they were trying to get DOJ to dismiss this case several years ago, that the test measured protection. And it's what they told the FDA in the clinical license applications, which

they were successful in getting because of these misrepresentations. And these same misrepresentations are reflected in the label.

So here's what we know, because there's a lot of talk about how great this vaccine is, right? So here's what we know about the Mumps vaccines that Merck has been selling the CDC for the past 20 years. There is no clinical data, at all, supporting the level of protection this vaccine affords. The only clinical data is from Protocol-7, and we heard what their witnesses and experts said about that test.

What you haven't, also, heard from Merck's counsel is this unprecedented resurgence in Mumps that has occurred since 2006. It is undisputed. Nowhere in Merck's presentation do they mention this. All of these great figures about the 99 percent reduction of disease are pegged to where the disease was in 1995. But if you look at from 2006 forward, it paints a very, very different picture. And it's own that the CDC, in its own words has said, "is of serious public health concern."

In these public statements that Merck's counsel represented about the FDA and the CDC trumpeting the vaccine, those same public statements, as we pointed out in our summary judgment papers, also raise the serious concern about the Mumps resurgence that they're still trying to figure out what the basis is for. This concern is so severe that some of the

world's leading experts have called for a new vaccine. One of them is the FDA's Steven Rubin, perhaps, the FDA's leading Mumps expert.

In writing a letter of support for NIH funding for new vaccine research, this is what he said, the resurgence has made "it quite clear that newer more immunogenic vaccines are needed. Dr. Biao He from the University of Georgia, who received NIH funding for a new vaccine, said this, in his application for the grant, "The resurgence underscores the urgency for new and effective Mumps vaccines to replace Merck's vaccines." Stanley Plotkin, who is, I think, by all accounts, the world's leading expert on Mumps, is calling for a new vaccine.

So, yes, the vaccine, to a point, was doing a very, very good job, but something happened, something, around the same timeline as these potency failures happened, and now, we have a very, very different product on the market. But we even asked Merck's witnesses -- we asked them, how is your vaccine? How effective is it? It's something you would think the manufacturer of the vaccine would know.

Dr. Krall, again, the designer of Protocol-7 and the one who ran the lab testing it, we asked him, with all of the testing that you've done with Protocol-7, how well does the vaccine protect against Mumps. We asked him that basic question. His answer, "I don't have an opinion on that."

This is the guy that ran the test to demonstrate that it provided sufficient protection. And we asked him the basic question, does it work? "I don't have an opinion on that."

Again, we asked Merck's corporate 30(b)(6) representative, Barbara Kuter, we asked her the same question. She -- that was one of the subjects she was there to testify to. She said she wasn't able to answer that. She said, well -- we asked if anybody at Merck could answer that, and she said, "I don't know."

Also, as we stated in the papers, Dr. Krall, during this testing, admitted to one of our Relators that the vaccine didn't work as well and was going to lead to the resurgence that we now see has happened. There are also several internal Merck documents that we've cited in our summary judgment papers where Merck, itself, besides these witnesses who didn't seem to have an opinion, they are internally questioning how well the vaccine works. They are raising concerns about how well the vaccine works, and they're wondering if the 96 percent figure on the label really needs to be lowered to reflect the actual protection that's provided.

So why is this a False Claims Act? Where is the fraud on the CDC? Merck's counsel is absolutely right. There was a lot of fraud on the FDA, no question, but this is not a fraud on the FDA case. Merck has independent duties to the CDC of full disclosure of any issues with the vaccine. They

negotiated with the CDC under the -- it's all reflected in the Third Circuit's Mazur decision.

But they negotiated with the CDC to protect themselves from product liability lawsuits. They said, hey, we're exposed. We need you to get out there if we're going to continue making this vaccine. We can't be exposed to all of these product liability suits. Vaccines are risky. And the CDC agreed that it would take on that liability. It would have the duty to warn the public about the benefits and risks of vaccination.

But the CDC insisted on a reciprocal duty. But you need to warn us, the CDC said, if you have any issues with your vaccine that might impact the benefits or risks that we are responsible for now providing. Merck negotiated that duty. They're trying to walk away from it. They clearly have a duty, but there are contractual duties, as well, and CGMP is one of them. It's not about, just, manufacturing. It's about assuring that your product has the potency and the protection that you are claiming.

So, that's the essence of where the responsibilities come. So, what did Merck share with the CDC about any of what I just said? Absolutely nothing. They didn't share that they had original potency failures. They didn't share that they had to double the potency of the vaccine, something you'd think the CDC would want to know. They didn't share that they

had to double the potency of the vaccine. They didn't share that they continued to have pervasive potency problems after they doubled the vaccine, so serious that internally for years, they recognized they were out of compliance, misbranded, non-marketable and potentially at risk of a recall or not even being able to sell the product at all, all from Merck's own mouth.

They didn't share the fraud they had to commit to succeed with Protocol-7. They didn't share that they misrepresented the results of those clinical trials. And I want to focus on the clinical trials, because Merck's counsel said, well, that's just between Merck and the FDA. Absolutely not.

Merck's own experts testified that what is a critical input to CDC decision-making on whether to recommend and purchase vaccines are the clinical trials that support licensure. That was Jonathan Temte, one of their main experts, said their decisions on vaccine purchasing and recommendations -- his words -- "largely depend" on the clinical trials that the CDC is mandated to review as part of that process.

William Atkinson, another one of Merck's experts, said the same thing. "The trial results" -- in his words -- "are critical information the CDC would need to understand in making vaccine purchase decisions."

Same thing with the label. The label isn't just between Merck and the FDA. As one of the Merck's witnesses said, and as reflected in the Mazur decision -- I'll start with that because it's clear. In Mazur, the Third Circuit says, that, because of this duty to warn, the main audience -- that's the Third Circuit speaking -- the intended audience of the label is the CDC, not the FDA. It's the CDC because it gives them an understanding of what they're supposed to be able to explain to the public.

So, all of these omissions, all of these direct misrepresentations, yeah, FDA, that was part of it -- that's why it's in our briefs. It tells you the extent to which Merck had to go. It shows their intent and their knowledge. But this is about the CDC. So, all of the fraud cases on the FDA, the Nargle case, which is one of their favorite cases, and another -- I can't even remember the names -- all of these fraud on the FDA cases are completely irrelevant here, because you did not have the same kind of direct responsibility to the purchasing agency.

You have to show, in those cases, that the FDA would have done something differently but for the misconduct at issue. That is not the case here. We're talking about an independent relationship with the CDC, independent duties, independent contractual requirements. These critical omissions and misrepresentations that have gone on for years,

gone on for years, are the essence of why this is a False Claims Act case.

The Third Circuit, in Wilkins, says that, False Claims Act cases take many shapes, but what they all have in common is either providing a product that the Government didn't pay for or providing one that violates key contractual regulatory or statutory obligations. You have both here. It fits into the factual falsity rubric. It fits into the implied certification rubric, and it falls into the fraudulent inducement.

What the CDC paid for was a vaccine that was free of potency and protection issues, that met the label specifications and the contract specifications that was backed by accurate and reliable clinical testing, and that worked, as well as Merck claimed, and on top of all that, with full disclosure -- full disclosure of any issues or concerns that Merck had about its vaccine. The CDC got none of that. This is exactly the type of case the False Claims Act was designed to cover.

So, now, let's talk about materiality, because I think with the full understanding of the gravity of the misconduct here, we can understand materiality. We're not just defending summary judgment on materiality. What Merck's counsel skipped over was the overwhelming and undisputed evidence of materiality, so much so that we believe

materiality should be granted in our favor on summary judgment.

None of this was discussed by Merck, so let me run it through, because there are so many different factors. First of all, who is in a better position to assess materiality than the agency which was the subject of fraud? The CDC is. And the CDC has spoken in this case on several occasions.

First off, twice, the CDC injected itself into this case with a letter that had to do with discovery and authorizing 30(b)(6) witnesses. And the letter from the Director of the CDC, and then there was a follow-up by the Deputy Director, said this, the CDC has a "clear interest" in the outcome of this case, because it is "critical" that they receive accurate information from vaccine manufacturers.

If that doesn't answer the materiality question by itself, I'm not sure what will, but we have a lot more from that. We have the United States, which, on numerous occasions, has injected itself into this case. Yes, they didn't intervene so many years ago. But when they didn't intervene, they made a point of saying, it had nothing to do with the merits. There are many reasons why the Government doesn't intervene.

And in the statement of interest they filed, challenging one of -- Merck was trying to get them to dismiss

the case. Instead, they filed a statement of interest rejecting Merck's main argument for dismissal. And in that statement, they said, the United States is the real party in interest here, and we have a "strong interest" in the outcome of this case.

As you know, they also filed a statement of interest in summary judgment on the very issue of materiality, and Mr. Sweet will likely speak to what their positions are on that. But if I can encapsulate them, I would point out that, first of all, they made it very clear, the United States, that Merck is applying the wrong standard on materiality. And what they also said is that, the Government's continuing purchases, in this context, where there is no actual knowledge, you have mere allegations. They know that. Maybe they even have a strong suspicion of wrongdoing, but that's not the standard under Escobar. It's actual knowledge. They don't have actual knowledge, and that comes clear from the statement of interest.

And, finally, in the statement of interest, the Government made it clear that even if the CDC did have actual knowledge, it doesn't undermine materiality in situations like this, where there are serious public health and safety reasons why you might want to continue purchasing here.

What are those reasons here? Mumps vaccines, until just a few months ago, when GSK finally was able to get into

the market, but up until, for the last 50 years, Merck was the only source for Mumps vaccine. So if the CDC stopped purchasing Merck's vaccines, they would have no Mumps vaccines at all. But even worse than that, you can't buy a Mumps vaccine alone. It only comes in a combination vaccine with Measles and Rubella.

So, if the CDC did what Merck said they should have done, if they cared about this case, they would had to cut off vaccinating millions of children a year for Measles, Mumps and Rubella. That doesn't give us any indication that they continued to buy it, even if they had actual knowledge, which they clearly did not.

But the DOJ issue doesn't stop there. We have cited numerous False Claims Act cases, which Merck's counsel dismisses as irrelevant but they are entirely on point. You know, the mine run of cases language from Escobar is exactly this. There have been -- we cited a half a dozen in our brief where the very facts at issue -- well, not the very facts. This is a very unique case. But the same kind of misconduct at issue was enough for the Government to bring False Claims Act enforcement actions against these defendants.

And I just want to highlight two of them. One is the McKesson case, which we cite in our papers. That involved CDC vaccine contracts under the Vaccine for Children Program, the same program here. It involved misconduct that impacted

the potency of the vaccine. And in successfully settling the matter, this is what the DOJ said, "Insuring the integrity and performance of Government contracts is paramount, especially when it impacts programs intended to protect young children," the same program at issue here. How is that not relevant to this case and the assessment of materiality? Merck does not say.

The other case I want to highlight is the Shire case. That was about a drug maker selling drugs that lacked clinical data -- sounds familiar -- and overstating the efficacy, exactly what's going on here. In successfully settling that case, this is what DOJ said, "We will be vigilant to hold accountable pharmaceutical companies that provide misleading information regarding drug safety and efficacy," exactly the issues on the table here.

But there is more, Your Honor. Escobar speaks to the essence of the bargain. The essential inquiry in a materiality assessment is the violations or the misrepresentations, omissions, do they go to the essence of the bargain? Effectiveness is the core essence of these vaccine contracts.

Their own experts admit -- and, I mean, it's not a far cry. You don't even need evidence, it's such a commonsensical point. But if we needed evidence, we can just look at their expert, Dr. Atkinson. This is his quote -- and

he was an expert who previously worked at the CDC -- "Vaccine effectiveness is obviously kind of the most important thing we deal with."

We can look at Merck's own papers. I don't know how they make this argument, and then have this in their papers, but they do. Their opposition papers at page 29, this is their quote, "CDC considers vaccine effectiveness the most important factor when evaluating vaccines."

This entire case is about effectiveness, potency and protection -- effectiveness. They admit it. It's the essence of the bargain, a clear indicia of materiality. But there's one more, and that's that the contract's provisions that we're talking about, the violations that we're talking about weren't just conditions of payment, and we spell this out in our brief. They were actual prerequisites for purchase.

Merck's counsel says we have no evidence. She's ignoring all the testimony that we got from the CDC. The CDC witnesses, both the ones that were the 30(b)(6) witnesses that the CDC produced, and the Merck experts, who were former CDC employees, they were uniform in saying that violations dealing with potency and protection, which are covered under CGMP, are prerequisites to purchase. Following CGMP is a requirement of -- it's in the contract.

And these witnesses were clear that if you're not violating -- if you are violating CGMP, we're not going to

contract with you. Even fraud, one of Merck's -- I'm sorry -- one of the CDC's 30(b)(6) -- oh, no, no, this was one of Merck's experts, Mr. Nichols -- or Dr. Nichols -- I don't remember -- he said that -- we asked, well, if one of your vendors committed fraud, would the CDC deal with them? I mean, let's just deal with common sense so stay that none of this would matter. And he said, "I don't think CDC would have wanted to contract with a vendor found guilty of committing fraud." This is their own experts who are backing this up.

So, we have the CDC speaking. We have the Department of Justice speaking. We have the prior FCA actions. We have the essence of the bargain, and we have prerequisites for purchase, which are way more material than conditions for payment. All of them undisputed from the documents -- Merck's own documents, Merck's own papers, Merck's own experts and the CDC witnesses.

So, let's talk about what they do talk about. They're real focused on materiality. They throw that out on the side and give it short shrift. And what they focus on, instead, is the decision of the CDC to continue purchasing. Well, I already spoke about, it's the only vaccine available up until a few months ago. You couldn't buy it unless they -- couldn't stop purchasing it unless they also got rid of Measles and Rubella.

So, what they're really asking for, Your Honor, is a

standard by which, if the Government gets a sniff or a whiff or even a suspicion of fraud, regardless of the product, regardless of the underlying circumstances, regardless of the availability of alternatives, they better stop purchasing or do something or they're going to lose their rights under the False Claims Act. Do you know what a dangerous precedent that would set? No court has ever adopted that.

They cite a bunch of cases. Not one of them deals with even a fraction of the facts at issue here with the type of product, bundled with another product, with all of these materiality evidence that we set forth. Virtually all of them deal with situations where lack of materiality was conceded or the Government came out and said that we don't care about this case. Very, very, very different than here.

And I think one of Merck's documents really speaks to this continued purchases argument the best. It was one of their consultants. They called the CDC and all of the other captive purchasers of Merck's Mumps vaccine, in their words, Merck's consultant, customers by force, not by choice -- customers by force. And that tells you a lot about the predicament the CDC has been in.

I want to talk -- because a lot of their focus is on this submission that Dr. Kessler made. What they haven't said is that they made their own submissions, two submissions actually, to rebut Dr. Kessler's position. And in those

submissions, they, essentially -- I don't want to speak too strongly, but I'm going to say it like I see it. They are continuing to perpetuate the fraud on the CDC that has been going on throughout this whole case, and I'll tell you why.

It's not just that they continued to say that their vaccine is safe and effective, even though they have no clinical data supporting that. And it's not just because they urged the Government to not take any action, even though they said that. It's this, in the very submission to the CDC and the FDA to rebut Dr. Kessler, they relied on the very falsified data that's at issue here.

And if you want to see it, it's Exhibit 205 -- Merck Exhibit 205 at pages 47 and 48. The Protocol-7 data that we have already seen was garbage and falsified, they relied on that to make their point that there's no case, here, so this is the fraud that's continuing.

They've also, I told you earlier, told the DOJ what Protocol-7 was about and didn't tell the truth on that either. So this is continuing. This is not something to put the Government on actual notice. Not only did they provide the falsified data, but they actually said that this demonstrates that the Mumps vaccine still provides protection.

So that's the materiality story in its entirety, filling in the major gaps that Merck left out. Let's talk about the effectiveness part, now, because they bandy about --

I mean, they had this nice chart that you saw which shows this precipitous drop. We've already talked about that. It's pegged to 1995. They don't really -- and it's on a scale that you don't really see what happens after 2006. In our reply brief, we do our own chart, which shows what happened from 1995. We kind of continue it on. And you see, it goes in the opposite direction with huge spikes.

So, let's forget about this 99 percent drop, because that's meaningless, at this point, since 2006. But let's talk about the 88 percent figure, because that's more current. And, yes, the FDA and the CDC are quoting to that number. But let's talk about what that number is.

That's not an average. It's a median. It's in the middle. And even their own slide, at page 11, shows what it is really is. It's a range. And the range that they have on their slide is 32 to 95 percent. So it's a range with a lower bound and an upper bound. And that lower bound, since 2006, keeps getting lower. It started at around 75 percent. Then it dropped into the 60s, and now, it's in the 30s.

What does that tell you, Your Honor? It tells you that, yeah, some of these vaccines may be 95 percent effective. Maybe a lot of them are 88 percent effective. Some of them are only 30 percent effective, and we don't know which ones are which. We don't know which -- which vaccine you give to this kid. We don't know if it's the one that's 30

percent -- and it's probably going to keep getting lower -- or if it's the 95 percent.

You know, here, CDC, here's all these vaccines. Can you imagine an auto supply company selling brakes to the Government and saying, yeah, 90 percent of these brakes work, but, you know, around ten percent, we're not so sure. We don't know which ones. Is the Government going to buy those from that supplier? No way. And that's what's going on here, and that's why CGMP and adequate assurances and the adulteration statutes are so critical, but Merck keeps skipping over that.

The potency failures, and the record is full of it -- we can show you a dozen documents -- Merck statistically predicted that up to eight percent of their vaccines were not going to comply with the potency specifications for the full shelf life. That's what raised the alarm, their statistical certainty.

And this wasn't some one-off statistician. This was done over many years, covering many different lots. There was a statistical certainty that up to eight percent of the lots were going to fail, and that's why they were fearing a recall. None of it shared with the FDA. That's why they were fearing a recall. That's why they called their product non-marketable and misbranded and out of compliance. And that's why this Protocol-7 -- it's not just some clinical trial that means

nothing. It means everything. But for that clinical trial, their market -- if anybody had found out about it, that product would have been pulled.

So, how does this relate to the 88 percent effective, some kids getting a 30 percent good shot, probably lower; some getting a 95 percent, and we don't know which one, Merck acknowledging, internally, at the highest level that eight percent are going to fail? That's what adequate assurances have, and they don't have that with this vaccine.

All of these other comments that are in their briefs, the second-guessing of the agency, you know, the -- I mean, there's so many that -- potency isn't part of the case. Efficacy and effectiveness are different. It's all a distraction from the key issues in this case.

There is a serious problem, a serious problem. If you could read the 500-page expert report of Dr. Kessler, you could see why he is so concerned. In his -- and if you listen to his deposition, he's shouting from the rooftops that something needs to be fixed here. This is a staple of the American Vaccination Program, and no one has any idea what's going on. And we have all the evidence to show what's behind it, and they've shared none of it with CDC.

If there wasn't a stronger case under the False Claims Act, I don't know what there would be.

THE COURT: Counsel?

MR. SWEET: Your Honor, I have some comments on materiality, as well. It might be better if Merck can speak after, and they can respond to anything I have to say? Thank you.

Your Honor, I'm going to speak for a few moments about the Government's position here. I am limiting my comments to the subject in the Government's statement of interest. And the Government takes no view on the sufficiency of the evidence in this case, but we do have a lot to say about the interpretation of materiality and the legal issues that are raised in the parties' briefs.

First, I just want to point out, because I think it's always good to start with the statute, itself. There's a definition of materiality in the False Claims Act. And I am citing to the Escobar case specifically has the definition as, "having a natural tendency to influence or be capable of influencing the payment or receipt of money or property."

That definition doesn't appear in Merck's presentation, but I think it's important to start there. The Government's knowledge is critical here. And, again, it's been pointed out by the parties that Escobar, which is the Supreme Court case, which really defines materiality and addresses the materiality prong, Justice Thomas specifically talks about where the Government has actual knowledge and what the Government's conduct is after actual knowledge.

I have some examples, if the Judge wants later at some point, about what actual knowledge could mean for the Government. But, at this point -- and the Government has knowledge of accusations, of allegations by Relators. The Government does not have actual knowledge. And allegations, alone, has little relevance to the materiality inquiry under the False Claims Act.

Merck states, throughout its briefing, that the Government must have concluded that Relators' allegations are untrue or otherwise not material, because the Government has actual knowledge of all of the facts and all of the evidence relating to this matter. That's just not true.

Merck's effort to represent that the Government knows, and to interject that conjecture into the materiality analysis is incorrect as a matter of law. The Government has knowledge of the allegations made by the Relators. The Government has not made any determination or drawn any conclusions --

THE COURT: Well, there's a big difference between knowing allegations, and all I know is the allegations, and the Government stopping there and saying, all I know is the allegations, and absolute knowledge over here. You can't stand up here -- or are you standing up here and saying, the FDA and the CDC did not have any of this information, did not explore it?

My understanding is the Government explored it for two years. So that's knowledge. Now, you want to tell me, actual knowledge versus allegations? Certainly, you knew more than allegations. And the Government knowing allegations, stepped in and did discovery, decided not to intervene, which is fine. It's not the case -- it's not the end of the case.

But, certainly, they made a due diligent look at what's going on, because they're protecting the people, the very people that are going to get these shots.

MR. SWEET: Your Honor, I'm glad you raised this. The Government --

THE COURT: So, I'm reading Escobar, too.

MR. SWEET: Yeah, Your Honor, the Government --

THE COURT: You're right, that's the case. They don't mention the statute, but they mention Escobar, which defines it. So I read it, and the definition of materiality is right there.

MR. SWEET: That's correct, Your Honor.

Let me speak to Your Honor's comments about what the Government knows and what the Government doesn't know.

THE COURT: Yeah, but more than allegations, though.

MR. SWEET: The Government knows allegations. The Government knows --

THE COURT: And they can't say, like, Sergeant Schultz, I know nothing now.

MR. SWEET: We didn't say we know nothing now.

THE COURT: That's what I was hearing you saying.

MR. SWEET: The declination, the Government's decision -- the Government investigated. They --

THE COURT: When she said -- counsel says, they know all this. They know all that -- we put it in front of them to let them investigate.

MR. SWEET: I think that says a lot about --

THE COURT: And they continued to buy. So it says a lot about, what?

MR. SWEET: Your Honor, if I can? If I may, there's a lot to say about -- in response to Your Honor's comments, and I appreciate Your Honor's comments. I think they're right on the mark.

In 2012, the Government declined to intervene, based on allegations in the original complaint. On the very same day, in April of 2012, the Relators filed an amended complaint. The amended complaint had new allegations. The amended complaint, then, went into discovery. There was years and years of discovery. The Government was aware of some of what was happening. The Government participated in some of what was happening.

But the Government did not take this case on. Again, we did not intervene in the case. We were not counsel to the case. We did not digest every bit of evidence. We

watched as the case progressed. And, under the False --

THE COURT: And the Government is, who?

MR. SWEET: -- Claims Act, Your Honor --

THE COURT: The Government is, who? The Government is the FDA?

MR. SWEET: The Government, in this case --

THE COURT: Is the Government the CDC?

MR. SWEET: Well, Your Honor, that's the point. The Government is a lot of things.

THE COURT: Right.

MR. SWEET: Right. The Government is the FDA. The FDA may know certain things.

THE COURT: So, you're --

MR. SWEET: The CDC may know certain things.

THE COURT: So, are you representing what the FDA knew? Are you representing what the CDC knew or followed during that period of time?

MR. SWEET: Your Honor, I'm saying that the Government's collective knowledge is expressed through the Department of Justice, and the Department of Justice is the party that speaks in court for the United States.

THE COURT: All right. And that's good, and I understand that.

MR. SWEET: And -- and, Your Honor --

THE COURT: But I'm looking at Escobar, which looks

at a holistic approach of materiality.

MR. SWEET: Correct.

THE COURT: So I understand that you're saying, look, take with a grain of salt when it's mentioned that the Government knew something. So they knew something, but what did they know? But the Government is coming up here and saying, collectively, we know nothing?

MR. SWEET: No. No, Your Honor, I never said nothing.

THE COURT: All right. So, what did you know?

MR. SWEET: Your Honor, we knew all sorts of -- we followed the case.

THE COURT: So you followed the case, okay?

MR. SWEET: So, when Merck says, the CDC and FDA, and I'm quoting here, "have all of the evidence to evaluate it", and they say that, "the DOJ, CDC and FDA know the entirety of Relators' falsity claims, including every pertinent piece of evidence that Relators say was withheld from the agency" -- that's at page two of their response to our statement of interest -- that's just simply not true.

THE COURT: It's hyperbolic, they call it.

MR. SWEET: Well --

THE COURT: They know all, but in other words, they have access to all. They were invited into all. What they knew, the DOJ is not going to say, we knew all.

MR. SWEET: Your Honor, no agency is all knowing.

THE COURT: Exactly.

MR. SWEET: Okay. This case progressed --

THE COURT: Exactly. Welcome to a courtroom, where there's hyperbolic statements.

MR. SWEET: Well, Judge, it's hyperbolic, but it's also the basis for saying that there's no materiality.

THE COURT: It is one basis for saying that, but it's not -- but you can't come up here and say, we know nothing.

MR. SWEET: I didn't say that, Your Honor.

THE COURT: Well, I heard that allegation.

MR. SWEET: I said we know allegations.

THE COURT: What do you know? So you know some things, but you don't know what those things are?

MR. SWEET: Your Honor, I can't -- I can't cite to you, right now, every piece of evidence we know.

THE COURT: Right.

MR. SWEET: We have had a lot of information available to us.

THE COURT: Right.

MR. SWEET: We've had -- we've had CDC witnesses deposed.

THE COURT: Right.

MR. SWEET: We've had discussions with the FDA, and

I'm not going to get into everything that we have internally discussed.

THE COURT: Right, because it would take us three days to go through it.

MR. SWEET: That's right, Your Honor.

THE COURT: Right, okay.

MR. SWEET: But, on the other hand, to suggest that the Government has full knowledge of every fact --

THE COURT: I agree with you. We're on the same page.

MR. SWEET: Okay. Your Honor, let me just continue on this issue, because this is where it goes from. I think we're on the same page that there is a difference between actual knowledge and knowledge of allegations, so I'll give you some examples, Your Honor.

THE COURT: Wait a second. There is, and we agree, but actual knowledge, you had actual knowledge to a lot of things, and you're saying, Judge, I'm not going to spend three days telling you what I have actual knowledge to.

MR. SWEET: Well, Your Honor, actual knowledge of the falsity of the -- of the -- whether there is falsity. That includes quite a lot of information. And, at no point since -- I'm not going to get into the Government's internal deliberations, but this case has been going on for years. The evidence has been developed over years. Testimony has been

taken. Experts have come in. I cannot say -- I cannot represent --

THE COURT: Right, right. Look, I understand. I understand what you're saying.

MR. SWEET: -- that the Government has distilled and synthesized everything, and said, all of the information has come to the Government, and we take this position. We know all. We are watching this case as it develops, and that is how the False Claims Act is designed.

The False Claims Act is designed to allow the Government to do an investigation. It doesn't require that we make a decision on the merits, and then we can decide to -- we can elect to intervene or decline.

We declined the original complaint in 2012. That's the point where discovery took off, and we were -- the Government is allowed to -- in fact, that is the design of the False Claims Act, to allow the Government to rely on Relators and their counsel to develop a case and try to put it on in court.

THE COURT: I understand that. And I understand what you are saying about actual knowledge. I don't know that I agree with you. I am reading Escobar. The DOJ can read whatever it wants. You can come here and say, look, we're out of the case, but you know what, we let it go on for ten years and follow it. So, therefore, actual knowledge, DOJ, under

those circumstances, we'd never have actual knowledge.

MR. SWEET: I can give you --

THE COURT: I'm assuming, if you have actual knowledge that this was causing a disease in children, you would have come in and said, look, we're stopping this --

MR. SWEET: Well, Your Honor --

THE COURT: -- right?

MR. SWEET: -- let me -- let me get to that, because the FDA's issues, and I think there was kind of a hit at the FDA about its obligation to inform the public about safety issues. This case is not about safety issues. The FDA looks at safety and effectiveness. This case is about effectiveness.

So I think it would be wrong to suggest --

THE COURT: Thank you, that -- that's --

MR. SWEET: -- and Merck's counsel did suggest --

THE COURT: -- counsel for defendants, if you listened carefully, said it was about safety and effectiveness.

MR. SWEET: Well --

THE COURT: But you're saying it's about effectiveness.

MR. SWEET: Well, yes, and I'm saying that --

THE COURT: Yes. But counsel was saying, look, if they're saying about safety, you had a responsibility to tell

the public.

MR. SWEET: That's correct.

THE COURT: And you didn't tell the public, because, Judge, it's about effectiveness.

MR. SWEET: That's correct.

THE COURT: Right, okay.

MR. SWEET: Okay. So the FDA is not falling on its obligations, here, because there is no safety issue; it's an effectiveness issue.

THE COURT: Okay, good.

MR. SWEET: Your Honor, if I can, I could give you a few examples --

THE COURT: We're on the same page with that.

MR. SWEET: Because Your Honor is interested in this knowledge issue, I'll give you a few examples of actual knowledge, because there are plenty of cases in which the Government, in a False Claims Act, after investigation, has actual knowledge.

One example, self disclosure. We have a lot of defendants who come in and self disclose. Then we have actual knowledge. We have discrete cases --

THE COURT: Wait a second. Wait a second. We can do all the generics you want about cases here and cases there, all right? Counsel is saying, look, they had knowledge of this Protocol-7 and the issues. The FDA came in, and they

worked with us with the issues.

They knew about the release potency versus the -- the discrepancy between the release potency and 24-month potency. FDA had actual knowledge of that. They came in, and they looked at it. The CDC, even though they were not dealing directly, came in, had actual knowledge of that.

Are you saying that the DOJ, even though they had actual knowledge of that, the DOJ had no actual knowledge of that?

MR. SWEET: Your Honor, what I am trying to say is that it's a matter of this argument on materiality --

THE COURT: Yes.

MR. SWEET: -- the suggestion that the Government had actual knowledge of all of the evidence and all of the pertinent records --

THE COURT: I agree with you. That's out the door.

MR. SWEET: Well, that's all I'm saying.

THE COURT: Okay, good.

MR. SWEET: That's what I'm -- so let me move forward.

THE COURT: Then we're done. What else do you have to say?

MR. SWEET: A few more things, Your Honor, if I may? And I can give you more examples of actual knowledge, but I think Your Honor has that issue, so --

THE COURT: I have the issue, and I am drilling down on the issue.

MR. SWEET: Okay.

THE COURT: Actual knowledge, the FDA, what did they have actual knowledge of? They had actual knowledge of the problem.

MR. SWEET: Okay.

THE COURT: That's what the argument is.

MR. SWEET: So, Your Honor, all of the statements in Merck's brief concerning -- and there were so many of them -- where materiality is based on continuing purchases, the failure to -- of the CDC to negotiate --

THE COURT: Continuing purchases, that's Escobar.

MR. SWEET: That's Escobar.

THE COURT: Right.

MR. SWEET: But there are other similar Government action and inaction that fall in the same category. For example, they raised the issue of the CDC's failure to negotiate the price of the vaccine once they became aware of the issue. They raise other issues of the Government's action and inaction. They raise out of state -- out of Court statements by FDA officials concerning effectiveness.

All of that, Judge, is presumptuous. All of that are conclusions. They do not have knowledge -- they do not have a basis to know why the Government did what it did. And

our statement of interest specifically addresses that. The FDA may act for all sorts of reasons.

THE COURT: They may, but, again, Escobar is saying, strong evidence. It's not the end of the case. It's strong evidence that, hey, the FDA comes in; they look at this. The CDC comes in. Actual knowledge as to the testing problem. The Whistle Blowers come in and say, look, there's a problem here. Okay, we're going to come in and look at it, and then the Government acts.

So, and then the Government acts, but then they say, like, the FBI, we never make a determination.

MR. SWEET: Your Honor, we are on --

THE COURT: It's like the DOJ, we never make a determination. We wait until the --

MR. SWEET: Your Honor --

THE COURT: -- the jury decides or the judge, but I get that. We're on the same page.

MR. SWEET: We're on the same page with that, as well, Your Honor.

THE COURT: Right.

MR. SWEET: All of this Government action can be --

THE COURT: Or inaction.

MR. SWEET: -- or inaction can be driven by numerous --

THE COURT: Or whether they'll wait and see for 12

years.

MR. SWEET: Well, it could be driven by numerous other factors.

THE COURT: But we'll continue to buy the product while we wait and see.

MR. SWEET: But to conclude, and that's the -- look, Merck brought a summary judgment --

THE COURT: To conclude, what? I like that word.

MR. SWEET: Merck brought a summary judgment motion saying that all of this Government action should show the Court that there is materiality. All we're saying is exactly what Escobar and Your Honor says. It's evidence.

THE COURT: Right.

MR. SWEET: It's not conclusive.

THE COURT: It's not.

MR. SWEET: Okay. Your Honor, I think you've got it, so I'm not going to belabor a lot of my argument here other than to say -- well, one more thing. Declination, it's come up over and over with respect to materiality.

The Government's decision to decline to intervene in the case is completely irrelevant to materiality.

THE COURT: I absolutely agree.

MR. SWEET: Okay. And the Third Circuit's Chief Judge Smith just spoke to this recently.

THE COURT: I always agree with the Third Circuit.

MR. SWEET: Okay, Judge.

THE COURT: Even when I disagree.

MR. SWEET: I understand, Your Honor.

THE COURT: I only let them know that in the elevator.

MR. SWEET: I have the same practice. And I'd just point out, Your Honor, that declined cases, the Government has collected since 1986, I think, 3.5 billion dollars in declined cases. The Government supports declined cases. The fact that we decline is not a suggestion that we're commenting on the merits of the case.

THE COURT: I whole-heartedly agree.

MR. SWEET: Okay. Judge, with the benefit of our intern from Drexel Law School, Mary Rose Babcock, in the back of the courtroom, we have a number of Circuit Court cases, and we left them at Circuit Court cases --

THE COURT: So, let me say hello to Mary Rose Babcock. Very good job. We love Drexel. Drexel sends some very nice students down here, so.

MR. SWEET: And her first assignment working with us this semester was to go back and look for Circuit Court cases that address these issues, the materiality issue, since the time we filed our statement of interest in 2000, right, a few years have passed.

So there are a few cases, if -- Your Honor, I can

tell you what they are now or I can submit a submission, a letter, but there are several Circuit Court cases, all of which support -- they would seem to support the suggestion -- the issue here that Government action or inaction, continuing sales, do not -- are evidence of materiality, and that evidence, unless there is no evidence on the other side, should go to a jury, and that there are many, many reasons that the Government may act, despite having knowledge, actual knowledge, even, of allegations.

THE COURT: So --

MR. SWEET: Yes?

THE COURT: -- I just feel like you're an advocate on this side, for the other side, even though you don't know nothing.

MR. SWEET: Your Honor, I'm an advocate --

THE COURT: It sounds like an advocacy position --

MR. SWEET: Your Honor --

THE COURT: -- for the plaintiffs, even though "I know nothing".

MR. SWEET: Your Honor --

THE COURT: In other words, you're preserving, hey, if they're going to get a few bucks, we get a few bucks, too. I don't understand what's going on here.

MR. SWEET: Absolutely not, Your Honor. I'm an advocate for the statute being interpreted properly.

THE COURT: Yes, and so, I -- I agree.

MR. SWEET: Okay.

THE COURT: It should be interpreted properly.

MR. SWEET: And so, there are a few other cases, Wolf Creek Federal Services, the Sixth Circuit Court of Appeals, Yates vs. Pinellas Hemotology and Oncology, the 11th Circuit --

THE COURT: But materiality doesn't go to the jury every time.

MR. SWEET: That's correct, Your Honor.

THE COURT: All right. So we're on the same page.

MR. SWEET: But it would seem to me that the issue of materiality would go to the jury unless the Court were to find that no reasonable juror could find for the non-movant in this case.

THE COURT: Correct, I agree.

MR. SWEET: Your Honor, unless you have any questions, finally, to conclude, the United States speaks exclusively for the -- I'm sorry -- the Department of Justice speaks exclusively for the United States in this case.

The Department of Justice has an established statutory authority, an established criteria to -- when it should intervene in a case and move for dismissal of the case, when it's in the Government's best interest. That has not happened here.

THE COURT: Well, listen, the Government could have stayed in, and they could have been an Intervener, and the question, still, of materiality is still on the table, wouldn't you agree? Even if you stayed in, and you said, Judge, it's material, I might say, it's not material.

MR. SWEET: Absolutely, Your Honor.

THE COURT: All right. So we're on the same page.

MR. SWEET: I think we are.

THE COURT: Yes.

MR. SWEET: Any further questions, Your Honor.

THE COURT: No, you did great. And thanks to the Drexel student for putting all of those -- did you interview for a new internship the day after you got the assignment?

(No audible response.)

THE COURT: I don't know how much further we can go on this. I know that you have some rebuttal, and you saved five minutes, but counsel took all 20 minutes of your five minutes.

MS. ELLSWORTH: Could I have three minutes, Your Honor?

THE COURT: I'll give you five minutes. Go ahead. Because we have another argument after this, you know.

MS. ELLSWORTH: Well, let me start with what I think was the most interesting thing that I heard today, which is that all --

THE COURT: Something I said, I hope?

MS. ELLSWORTH: Hopefully, it's something you will say.

I told you that effectiveness was the most important factor for the CDC. Relators' counsel stood up and told you, effectiveness data is the most important factor for the CDC, and then the United States stood up and told you, effectiveness is the most important factor to the CDC.

Well, if you want to talk about actual knowledge, the CDC develops its own effectiveness data. Merck has nothing to do with that. It is between the CDC, and the State and local health officials, and the CDC has known that the effectiveness data shows an 88 percent median effectiveness rate, and it hasn't shifted.

The CDC has known the range the Relators counsel told you has changed. The range has, but the median hasn't. And so, on that point, alone, I think all of the parties agree that, on this thing, on this element, there is actual knowledge by the CDC, and it's the most important driver.

I'll also note, on actual knowledge --

THE COURT: They don't agree with that, I guarantee it. So what's your next point? Go ahead.

MS. ELLSWORTH: The Relators and the United States said, the U.S. didn't have actual knowledge here, but if you look at Merck Exhibit 205, that is the Dr. Kessler

submissions. That is 30 pages of submissions from Dr. Kessler laying out their best story. They absolutely -- the CDC and the FDA, the Commissioner of the FDA and the Director of the CDC and a whole bunch of other public health officials at HHS, everyone who Dr. Kessler wanted to send this to, received it, so that the FDA and the CDC have that knowledge to.

It's not a lack of knowledge here, that's the issue. It's that that knowledge wasn't persuasive to the CDC in changing any of its purchasing habits.

And the argument that because Merck defended itself to the CDC, that meant the agency couldn't evaluate whether or not this was valid concern really makes no sense, when you think that the Relators are going to ask a lay jury to make that assessment. That is what would be the absurd outcome here, and that's why the Nargle and the D'Agostino case that we cited in our papers, and I didn't hear the U.S. respond to, I think are really important ones for the Court to look at.

The False Claims Act is not about second-guessing agency judgment, and that is, really, what the Relators are asking you to do today.

And I think I'll save the rest of what I have, Your Honor.

MR. SCHNELL: Your Honor, may I have two minutes, please?

THE COURT: Sure.

MR. SCHNELL: On the CDC knowledge, what I omitted from, also, when I spoke, we deposed the 30(b)(6) witnesses. We asked them, do you have any knowledge of any of the potency issues in the complaint. This is years after the complaint. Do you have any knowledge? They said, no.

They didn't even know that Merck had had to double the Mumps' potency. They had no knowledge of the clinical trial fraud. They had no knowledge of anything. This is their own witnesses. That speaks directly to what the CDC knows and doesn't know, not this conjecture about, well, they must have done something; they must have gotten something.

And, again, with the exhibit that they're pointing to, 205, I would point you to pages 47 and 48, where they included the falsified information.

The most important point that we haven't touched is, now, we finally have another Mumps vaccine. It's the GSK vaccine. It's only been approved for a few months. The CDC has already started to shift some of its purchases away from Merck to CDC. That's one action that has changed.

Other actions, they said the CDC has done nothing. The CDC has done a lot to investigate the resurgence. They've set up investigatory panels, a working group exclusively devoted to this. They changed their vaccine recommendations in 2006 from -- first, they thought you only needed one shot. They changed it to two shots. They changed it, again, in 2017

to three shots for outbreaks, and there are internal documents from the CDC, which we have in our papers, referencing their "vital need" for a second supplier.

So to say that the CDC has done nothing is just not true. It's all about conjecture. The CDC has done stuff, including shifting their purchases, starting to shift their purchases, so you cannot say that is beyond dispute that that is any indication of how the CDC feels about the allegations in this case.

And I'll stop there.

THE COURT: All right.

Anything else, Counsel?

MS. ELLSWORTH: I would just note that on these questions about the CDC witnesses who were deposed, it was Relators' burden to put a document in front of the CDC and ask that witness if it would have changed anything about CDC's purchasing if the witness had known that. They didn't do that, because they wouldn't have liked the answer.

THE COURT: All right. Anything else? A last word?

MR. SCHNELL: We did put those questions before Merck's experts, who were CDC witnesses, and the CDC witnesses, and they reaffirmed, these are prerequisites for purchasing, so they absolutely did support materiality here.

THE COURT: All right, Counsel, thank you.

ALL COUNSEL: Thank you, Your Honor.

THE COURT: All right. Chris, we'll take ten minutes. We'll take ten minutes.

COURTROOM DEPUTY: All rise.

(Proceedings concluded at 11:40 a.m.)

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C E R T I F I C A T I O N

I, Jacqueline Mullica, court approved transcriber, certify that the foregoing is a correct transcript from the official electronic sound recording of the proceedings in the above-entitled matter on January 24, 2023 from 10:11 a.m. to 11:40 a.m.

/s/Jacqueline Mullica January 25, 2023

JACQUELINE MULLICA

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